



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0155]

Veterinary Feed Directive Common Format Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry #233 entitled "Veterinary Feed Directive Common Format Questions and Answers." On June 3, 2015, FDA published a final rule that revised the Agency's veterinary feed directive (VFD) regulations. During the rulemaking process, FDA received a few comments requesting that we require a uniform VFD form. Although we declined this request because we think that requiring a specific VFD form would be too prescriptive, we acknowledge that a common VFD format would help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD and are issuing this draft guidance to recommend a common VFD format.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information

submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2010-N-0155 for "Veterinary Feed Directive Common Format Questions and Answers." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dragan Momcilovic, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5944, dragan.momcilovic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #233 entitled "Veterinary Feed Directive Common Format Questions and Answers."

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. In passing the ADAA, Congress created a new regulatory category for certain animal drugs used in or on animal feed called VFD drugs. VFD drugs are new animal drugs intended for use in or on animal feed which

are limited to use under the professional supervision of a licensed veterinarian. FDA published final regulations at § 558.6 (21 CFR 558.6) implementing the VFD-related provisions of the ADAA in 2000. On June 3, 2015 (80 FR 31707), FDA published a VFD final rule that revised those VFD regulations and introduced clarifying changes to specified definitions.

During the latest rulemaking process, FDA received a few comments requesting the Agency to require a uniform VFD format. We declined this request because we thought that requiring a specific format would be too prescriptive. However, we acknowledge that a common VFD format would help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD.

We are issuing this draft guidance to recommend a common VFD format. In the draft guidance, we use the term "VFD" to refer to the form used to convey the VFD order. This draft guidance describes the requirements in § 514.1(b)(9) (21 CFR 514.1(b)(9)) for sponsor submission of a VFD to FDA as part of the application process for approval of a new animal drug for use in or on animal feed as a VFD drug, as well as the required and optional information to be included on the VFD. This draft guidance provides examples that illustrate how a common VFD format might appear and how some of the information on the VFD may be prepopulated by a sponsor.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Veterinary Feed Directive Common Format Questions and Answers." It does not establish any rights for any person and is not binding on FDA or the public. You can

use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in § 514.1 have been approved under OMB control number 0910-0032. The collections of information in § 558.6 have been approved under OMB control number 0910-0363.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: November 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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